Supreme Court, U.S.
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No. 95-886

IN THE
Supreme Court of the United States
OCTOBER TERM, 1995

LORA LOHR AND MICHAEL LOHR,

Cross-Petitioners,

v.

MEDTRONIC, INC.,

Cross-Respondent.

On Cross-Petition for Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

BRIEF IN OPPOSITION TO CONDITIONAL CROSS-PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether the Federal Food, Drug, and Cosmetic Act preempts state common law claims alleging defective manufacturing and labeling of a medical device that the Food and Drug Administration reviewed and affirmatively authorized for marketing under the Act's complex regulatory scheme.

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No. 95-886

IN THE
SUPREME COURT OF THE UNITED STATES
OCTOBER TERM, 1995

LORA LOHR AND MICHAEL LOHR,
Cross-Petitioners,
v.
MEDTRONIC, INC.,
Cross-Respondent.

On Cross-Petition for a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

BRIEF IN OPPOSITION TO CONDITIONAL CROSS-PETITION FOR A WRIT OF CERTIORARI

Cross-respondent Medtronic, Inc. hereby opposes the conditional cross-petition for a writ of certiorari filed by Lora and Michael Lohr. The cross-petition should be denied, because there is no substantial or irreconcilable conflict among the federal courts of appeals regarding the issues presented.

STATEMENT OF THE CASE

Pursuant to Supreme Court Rule 15.2, Medtronic sets forth below clarifications to cross-petitioners' description of the device at issue in this case.

This case arises from allegations concerning Medtronic's Model 4011 pacemaker lead. *See, e.g.*, Conditional Cross-

Petition for a Writ of Certiorari ("Cross-Petition") at 7. The Model 4011 lead is part of a pacemaker system implanted in the body to assist the heart's natural beat. Pacemaker leads such as the Model 4011 transmit small electrical pulses to the heart from another part of the implanted system—a pacemaker pulse generator—and return signals from the heart to the pulse generator. *Medtronic, Inc. v. Lohr*, No. 95-754, Petition for Writ of Certiorari ("Petition") at 6-7. The Food and Drug Administration ("FDA") has assigned pacemaker leads of the type at issue in this case to Class III and permitted marketing clearance through the "510(k)" substantial equivalence process. 21 C.F.R. § 870.3680(b), (c) (1995).

Some portions of the Eleventh Circuit's opinion characterize the device at issue correctly as the Model 4011 lead, but other portions mischaracterize the device as the Activitrax Model 8403 pacemaker. *See Medtronic, Inc. v. Lohr*, No. 95-754, Appendix to Petition for Writ of Certiorari ("Pet. App.") at 5a-6a. The Activitrax Model 8403 is the pacemaker pulse generator alleged to have been implanted in Lora Lohr together with the Model 4011 lead and is a different device than the lead. In contrast to the Model 4011 lead, the Activitrax Model 8403 received marketing clearance under the premarket approval process rather than the 510(k) process. 51 Fed. Reg. 25,260 (July 11, 1986) (announcing FDA premarket approval of Activitrax Model 8403). Because cross-petitioners' claims relate to the lead rather than the pulse generator implanted in Lora Lohr, the Activitrax Model 8403 was not at issue in the court below. Motion for Summary Judgment and Request for Oral Argument at 2 (R1-36-2); Eleventh Circuit Brief of Appellee Medtronic, Inc. at 3

n.1. The Eleventh Circuit's erroneous description of the device at issue did not affect the substance of its holding, however, because the court correctly characterized the device as a Class III 510(k) device. Pet. App. at 23a.[1]

The cross-petition shares some of the confusion evident in the Eleventh Circuit's opinion, describing the device both as a pacemaker lead and as a pacemaker. *See* Cross-Petition at 5-8. However, this error is not material to cross-petitioners' analysis. Like the Eleventh Circuit, cross-petitioners concur that the device at issue is a Class III 510(k) device. *See id.* at 5-6. As a result, cross-petitioners agree with Medtronic that the preemption issues presented for review in this Court arise in the context of federal and state requirements applicable to a Class III 510(k) device. *See id.* at 5-6.

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[1] Medtronic noted the error regarding the Activitrax Model 8403 in its Petition for Rehearing and Suggestion of Rehearing In Banc, which the Eleventh Circuit denied on August 15, 1995.

ARGUMENT

I. THERE IS NO SUBSTANTIAL OR IRRECONCILABLE CONFLICT AMONG THE COURTS OF APPEALS CONCERNING THE ISSUES PRESENTED IN THE CROSS-PETITION

A. The Eleventh Circuit's Decision Regarding Preemption of Labeling and Manufacturing Claims Is Consistent with Decisions of All Other Courts of Appeals that Have Decided the Same Issues

The question presented to the court below was whether the Federal Food, Drug, and Cosmetic Act ("FDCA") preempts state common law claims alleging defects in the design, manufacturing, and labeling of a Class III 510(k) device. Pet. App. at 6a-8a. The Eleventh Circuit ruled against cross-petitioners on two of the three theories of liability, holding that the FDCA preempts manufacturing and labeling claims but does not preempt design claims. *Id.* at 36a. Cross-petitioners now seek review of their adverse ruling on the manufacturing and labeling claims. Cross-Petition at 13.

In its petition for writ of certiorari, Medtronic explained that the First, Third, Fourth, and Fifth Circuits are the only other courts of appeals that have decided whether the FDCA preempts manufacturing and labeling claims involving a Class III 510(k) device. Petition at 19 & n.15; *Mendes v. Medtronic, Inc.*, 18 F.3d 13 (1st Cir. 1994); *English v. Mentor Corp.*, 67 F.3d 477 (3d Cir. 1995); *Duvall v. Bristol-Myers-Squibb Co.*, 65 F.3d 392 (4th Cir. 1995); *Feldt v. Mentor Corp.*, 61 F.3d 431 (5th Cir. 1995). These four decisions are consistent with the Eleventh Circuit's holding that the Act preempts manufacturing and labeling claims. Petition at 19 & n.15. As a result, there is no conflict among the five

circuits that have decided the precise issues raised by the cross-petition.

Cross-petitioners acknowledge that the Eleventh Circuit's holding regarding labeling and manufacturing claims is consistent with the First and Fifth Circuit decisions noted above. Cross-Petition at 13. Furthermore, the cross-petition does not refute that the Third and Fourth Circuit decisions cited above are consistent with the Eleventh Circuit's holding regarding the same issues. *See id.*[2]

Unable to identify a direct circuit conflict on the issues presented in the cross-petition, the Lohrs reiterate the conflict concerning the design claim issues raised in Medtronic's own petition for certiorari. *Compare* Cross-Petition at 13 *with* Petition at 11-17. In its petition, Medtronic made clear that decisions of the Third and Fourth Circuits affirming preemption of design claims conflict directly with decisions of the Fifth and Eleventh Circuits denying such preemption. Petition at 11-13. Cross-petitioners do not oppose Medtronic's petition or its argument that the circuit conflict justifies Supreme Court review of the design claim issue.

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[2] Cross-petitioners do assert that the Eleventh Circuit's ruling regarding manufacturing and labeling claims conflicts with lower court decisions holding that "*general* FDA requirements cannot trigger preemption." Cross-Petition at 13-14. The only court of appeals opinion cross-petitioners cite is *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243 (5th Cir. 1989), which denied preemption of manufacturing claims because there was no federal manufacturing requirement applicable solely to the device at issue. In the *Feldt* case cited above, the Fifth Circuit resolved this inconsistency. The *Feldt* court explicitly stated that "since *Moore*, it has become clear that these regulations need not be device-specific; they need only apply generally to the device at issue" to preempt common law claims. *Feldt*, 61 F.3d at 436.

Medtronic, Inc. v. Lohr, No. 95-754, Response to Petition for a Writ of Certiorari at 1-2. Indeed, the cross-petition affirms Medtronic's argument that there is a conflict among the Third, Fourth, Fifth, and Eleventh Circuits concerning the preemption of design claims. *See* Cross-Petition at 13. However, this conflict regarding design claims provides no support for the cross-petition, which seeks review of the Eleventh Circuit's ruling regarding manufacturing and labeling claims and does not relate to design claims.

Similarly, cross-petitioners emphasize that there is a direct circuit conflict on the question whether the 510(k) process itself preempts common law claims. Cross-Petition at 12-13. The Eleventh Circuit ruled in cross-petitioners' favor on this issue, holding that the 510(k) process does not preempt manufacturing and labeling claims. Pet. App. at 30a, 32a. Because the cross-petitioners did not receive an adverse ruling on this issue, it is not properly within the scope of the cross-petition. In contrast, the issue is central to Medtronic's petition, because the primary federal requirements governing design of 510(k) devices are imposed through the 510(k) process itself rather than through independent substantive design standards. Petition at 15-16, 20. The circuit conflict regarding the preemptive effect of the 510(k) process provides no support for the cross-petition and instead underscores the need for Supreme Court review of the issues raised by Medtronic's petition.

B. The Conflict Between the Eleventh Circuit's Decision and a Ninth Circuit Preemption Decision Does Not Justify Granting the Cross-Petition

Cross-petitioners argue that the principles underlying the Eleventh Circuit's ruling regarding labeling and manufacturing claims conflict with a recent Ninth Circuit decision holding that common law claims are not subject to preemp-

tion under the FDCA. Cross-Petition at 10-11, 13 (citing *Kennedy v. Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995)). Cross-petitioners' primary argument is that this conflict justifies Supreme Court review. Cross-Petition at 10-11, 13. The cross-petition even argues on the merits that the position adopted by the Ninth Circuit in *Kennedy* is correct. Cross-Petition at 16-22.[3]

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[3] The second section of the cross-petition sets forth the argument on the merits. *See id.* Because consideration of the cross-petition does not involve a ruling on the merits, Medtronic will not respond to the merits arguments. Medtronic does, however, note that the Ninth Circuit is the only court of appeals to hold that common law claims are not subject to preemption. The nine other circuits that have confronted the question (including the Sixth Circuit, in a case decided since Medtronic's petition was filed) have held that common law claims are subject to preemption. *See, e.g., King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993); *Becker v. Optical Radiation Corp.*, 66 F.3d 18 (2d Cir. 1995); *Gile v. Optical Radiation Corp.*, 22 F.3d 540 (3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994); *Duvall v. Bristol-Myers-Squibb Co.*, 65 F.3d 392 (4th Cir. 1995); *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993); *Martin v. Telectronics Pacing Systems, Inc.*, 70 F.3d 39 (6th Cir. 1995); *Slater v. Optical Radiation Corp.*, 961 F.3d 1330 (7th Cir.), *cert. denied*, 113 S. Ct. 327 (1992); *Martello v. Ciba Vision Corp.*, 42 F.3d 1167 (8th Cir. 1994), *cert. denied*, 115 S. Ct. 2614 (1995); *Duncan v. Iolab Corp.*, 12 F.3d 194 (11th Cir. 1994) (per curiam). The court below referred to the overwhelming authority favoring preemption and did not, as cross-petitioners suggest, imply that it might have concluded that common law claims are not preempted in the absence of binding precedent. *Compare* Pet. App. at 11a & n.7 *with* Cross-Petition at 9, 11, 16.

Medtronic does object to the evidentiary materials submitted in support of the merits arguments at pages 4a through 7a of the cross-petition Appendix. These materials are not in the record and therefore are not properly before this Court.

The conflict with *Kennedy* does not justify granting the cross-petition, because the Ninth Circuit may resolve the conflict upon further review. Since the time that its petition for certiorari was filed, Medtronic has learned that there is a pending petition for rehearing and suggestion of rehearing in banc in the *Kennedy* case. Medtronic also has learned that the Ninth Circuit has requested and received a response to the *Kennedy* rehearing petition. The rehearing petition argues that the *Kennedy* ruling is wrong on the merits, citing decisions of the numerous other circuits that have affirmed preemption of common law claims under the FDCA. Petition for Rehearing and Suggestion for Rehearing En Banc, *reprinted in* Appendix hereto at 7a-19a. The rehearing petition also explains that the *Kennedy* holding conflicts with *dicta* in *Anguiano v. E.I. du Pont de Nemours & Co.*, 44 F.3d 806 (9th Cir. 1995), in which another panel of the Ninth Circuit indicated that the FDCA does preempt state common law claims. *Id.* at 7a (citing *Anguiano*, 44 F.3d at 809). The conflict between *Kennedy* and the court below does not justify granting the cross-petition, because the Ninth Circuit may resolve the conflict without intervention by this Court.

Furthermore, even if the Ninth Circuit denies further review, this Court can resolve the conflict with *Kennedy* without granting the cross-petition. Medtronic's original petition squarely presents the question whether the FDCA preempts common law claims. Unlike the cross-petition, Medtronic's petition presents this Court with the opportunity to address the conflict with *Kennedy* in the context of a broader and irreconcilable disagreement among the circuits concerning the scope of preemption.

C. The Eleventh Circuit's Statements Concerning Claims for Failure to Comply with Regulatory Requirements Do Not Provide a Proper Basis for Supreme Court Review

The court below indicated that there is no exception to preemption for state common law claims that allege violations of federal regulatory requirements. Pet. App. at 12a-14a. The cross-petition asserts that the Eleventh Circuit's statement on this issue conflicts with decisions of the Third, Seventh, and Eighth Circuits. Cross-Petition at 14-15. For two reasons, the Eleventh Circuit's statements concerning such claims do not provide a proper basis for Supreme Court review.

First, the Eleventh Circuit's statements on this preemption issue are *dicta* and therefore could not have created a substantial or irreconcilable conflict with holdings of other courts. There was no claim for failure to comply with regulatory requirements properly before the Eleventh Circuit. The court could only reach the issue by "assum[ing], arguendo, that Florida common law would recognize an action whose standard of care is defined by the standards of the MDA and that Appellants' complaint may be read broadly enough to encompass such an action." Pet. App. at 13a n.8. Both assumptions are erroneous. The complaint in this action does not assert any claim for failure to comply with regulatory requirements. Complaint (R. 1-3). In addition, cross-petitioners have never established that such a claim may be asserted under Florida law.[4] Because cross-petitioners never pleaded a

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[4] Under Florida law, it may be inappropriate to instruct the jury that the doctrine of negligence per se applies, even if an alleged statutory

(Footnote cont'd on next page)

claim for failure to comply with regulatory requirements, the Eleventh Circuit's comments regarding preemption of such claims are *dicta*.[5]

Furthermore, because cross-petitioners did not plead a claim for failure to comply with regulatory requirements, the parties did not address preemption of such claims before the district court or in their opening briefs in the Eleventh Circuit. Cross-petitioners raised the issue for the first time in footnotes to their Eleventh Circuit reply brief. Appellants' Reply Brief at 16 n.5, 17 n.6. Under Eleventh Circuit precedent, it is "well settled" that a party cannot argue a new non-jurisdictional issue in its reply brief when, as in this case, it did not raise the issue in its opening brief. *Tallahassee*

(Footnote cont'd from previous page.)

violation typically constitutes negligence. *Underwriters at LaConcorde v. Airtech Servs., Inc.*, 493 So. 2d 428, 431 (Fla. 1986) (Boyd, J., concurring in part and dissenting in part). Furthermore, the Florida courts have not resolved definitively whether negligence per se even applies to violations of administrative regulations as well as to violations of statutes. *Id.* at 430. It is even less clear whether negligence per se applies to violations of federal regulations. *See, e.g., Murray v. Briggs*, 569 So. 2d 476, 480 (Fla. Dist. Ct. App. 1990) ("[A]lthough several courts seem comfortable with the concept, we are not satisfied that a federal regulation should necessarily control state law questions of negligence by enlarging common law duties or creating new duties.") (footnote omitted), *review denied*, 581 So. 2d 165 (Fla. 1991); *see also Cadillac Fairview of Fla., Inc. v. Cespedes*, 468 So. 2d 417, 421 (Fla. Dist. Ct. App.) (OSHA violation not dispositive on state law questions of negligence or products liability), *review denied*, 479 So. 2d 117 (Fla. 1985).

[5] The Eleventh Circuit refused to file a supplemental brief in which Medtronic explained that no such claim was or could be properly pleaded. *See* Pet. App. at 7a n.4.

Memorial Regional Medical Ctr. v. Bowen, 815 F.2d 1435, 1446 n.16 (11th Cir. 1987), *cert. denied*, 485 U.S. 1020 (1988). The Eleventh Circuit agreed that the issue appeared first in the reply brief but nonetheless "exercise[d] discretion to reach this question." Pet. App. at 13a. This exercise of discretion was nothing more than a statement of *dicta*; because they were raised too late, cross-petitioners' arguments concerning these claims were "not properly before the reviewing court." *United States v. Oakley*, 744 F.2d 1553, 1556 (11th Cir. 1984).

Second, there is no substantial or irreconcilable conflict between the Eleventh Circuit's *dicta* and the Third and Eighth Circuit decisions identified by cross-petitioners, *Michael v. Shiley, Inc.*, 46 F.3d 1316 (3d Cir.), *cert. denied*, 116 S. Ct. 67 (1995), and *National Bank of Commerce v. Kimberly-Clark Corp.*, 38 F.3d 988 (8th Cir. 1994); *see* Cross-Petition at 14-15 & 15 n.8. In *Michael*, the Third Circuit affirmed preemption of a claim for defrauding FDA in violation of federal requirements, concluding that "[u]nder the MDA, states have no authority to police [the manufacturer's] compliance with the FDA's procedures." 46 F.3d at 1329. This holding is wholly consistent with the Eleventh Circuit's statement that claims for violation of regulatory requirements are preempted. Pet. App. at 12a-14a. The *Michael* court also denied preemption of an express warranty claim on the ground that it would merely enforce federal requirements. 46 F.3d at 1328. The Eleventh Circuit below did not regard the *Michael* holding on the express warranty claim as a significant inconsistency, citing *Michael* as support for

its *dicta* regarding claims for failure to comply with regulatory requirements. Pet. App. at 13a-14a & 14a n.9.[6]

Similarly, in *National Bank of Commerce*, the Eighth Circuit affirmed preemption of claims alleging failure to comply with regulatory requirements. 38 F.3d at 998-99 (Loken & Fagg, J.J., concurring). Although the Eighth Circuit also stated that such claims would not be preempted under other facts, *see id.* at 993-94, the court below regarded *National Bank of Commerce* as consistent with its *dicta*, citing the decision as supporting authority. Pet. App. at 14a & n.9.

Because the Eleventh Circuit has concluded that its *dicta* are in harmony with *Michael* and *National Bank of Commerce*, those decisions do not present a conflict justifying review in this Court. Although the decisions in *Michael* and *National Bank of Commerce* do contain internal tensions regarding the scope of preemption of claims for failure to comply with regulatory requirements, this Court should leave resolution of those tensions to future decisions of the Third and Eighth Circuits.

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[6] This Court recently denied review of the *Michael* court's ruling on the express warranty claim. *See* Petition for Certiorari at 11, *Shiley, Inc. v. Michael*, No. 94-1971, *cert. denied*, 116 S. Ct. 67 (Oct. 2, 1995).

CONCLUSION

The cross-petition should be denied. Although Medtronic's unopposed petition for certiorari raises a substantial and irreconcilable conflict among the circuits concerning the preemption of design claims, there is no such conflict concerning the manufacturing and labeling claim issues presented in the cross-petition. This Court should deny the cross-petition and restrict review to the critical design claim issues raised in Medtronic's unopposed petition for certiorari.

Respectfully submitted,

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APPENDIX

No. 94-15197

IN THE
UNITED STATE COURT OF APPEALS
FOR THE NINTH CIRCUIT

CHARLOTTE KENNEDY and ROBERT L. KENNEDY,
Plaintiffs and Appellants,
v.
COLLAGEN CORPORATION,
Defendant and Appellee.

Appeal from the United States District Court
for the Northern District of California

Charles A. Legge,
District Judge Presiding

PETITION FOR REHEARING AND SUGGESTION FOR REHEARING EN BANC

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I. WHAT IS AT STAKE

The Courts of Appeals for the First, Second, Third, Fourth, Fifth, Seventh, Eighth, and Eleventh Circuits have ruled, in 17 decisions, that state tort claims against producers of FDA-approved Class III medical devices are expressly preempted by the Medical Device Amendments of 1976. No circuit—until now—has ruled to the contrary.

A Class III medical device is generally used where there is a medical problem or condition, and a physician has determined that the device is necessary or appropriate. If the condition worsens, or fails to improve, or the patient develops some unrelated condition, there is a tendency to blame the device. Many thousands of tort claims theoretically could be brought against medical device producers annually.

The Panel's decision ensures that every plaintiff in the United States who claims injury caused by a Class III medical device will, if at all possible, file suit within the Ninth Circuit. As the West is home to a great many of the country's medical device producers—including biotechnology firms at the cutting edge of device innovation—the district courts can look forward to a substantial increase in business.

Before it imposes a burden of such magnitude on the Circuit's trial courts, the Court should review this case to determine whether the many circuit judges elsewhere in the nation who have considered the issue were indeed wrong, or whether the Panel is wrong.

II. INTRODUCTION AND STATEMENT OF COUNSEL

Collagen Corporation ("Collagen") seeks rehearing *en banc* of the Panel's decision concerning an issue of national significance under the Medical Device Amendments of 1976

("the MDA"), 21 U.S.C. §§ 360c-3601 (Supp. 1995). The Panel held:

> general state tort law is *not* preempted by the MDA.

Kennedy at 13538 (Reinhardt J., concurring) (emphasis in the original). However, another Ninth Circuit panel has said:

> [i]n promulgating the MDA, Congress expressly intended to preempt state tort law.

Anguiano v. E. I. DuPont De Nemours & Co. Inc., 44 F.3d 806, 809 (9th Cir. 1995). While the latter statement fairly may be called dictum, it is scarcely a throwaway line; to the contrary, it is an important element in a careful analysis of the purpose, structure, and preemptive scope of the MDA. Moreover, it is consistent with the holdings of every other circuit that has squarely addressed the issue.

The First Circuit:

> [T]he MDA expressly preempts Ms. King's state law tort claims.

King v. Collagen Corp., 983 F.2d 1130, 1136 (1st Cir.), *cert. denied*, 114 S.Ct. 84 (1993). Accord: *Talbott v. C. R. Bard Inc.*, 63 F.3d 25 (1st Cir. 1995); *Mendes v. Medtronic. Inc.*, 18 F.3d 13 (1st Cir. 1994).

The Second Circuit:

> Becker's state tort claims are preempted by the MDA.

Becker v. Optical Radiation Corp., 66 F.3d 18 (2nd Cir. 1995).

The Third Circuit:

> [The MDA] preempt[s] state law strict liability and negligence claims as impermissible attempts to impose additional safety or effectiveness requirements on medical device manufacturers.

English v. Mentor Corp., ____ F.3d_____, 1995 WL 573387 (3d Cir. Sept. 29, 1995). Accord: *Michael v. Shiley. Inc.*, 46 F.3d 1316 (3d Cir.), *cert. denied sub nom. Shiley. Inc. v. Michael*, 63 U.S.L.W. 3874, 1995 WL 349005 (1995); *Gile v. Optical Radiation Corp.*, 22 F.3d 540 (3d Cir.), *cert. denied*, 115 S.Ct. 429 (1994).

The Fourth Circuit:

> [21 U.S.C. § 360k(a)] expressly reveals congressional intent that the MDA preempt state imposed requirements that are different from or additional to those applicable to the device under [the MDA]. . . . The question then becomes whether state law claims may impose requirements within the meaning of 360k. We conclude they may.

Duvall v. Bristol-Myers-Squibb Co., 65 F.3d 392, 397 (4th Cir. 1995) .

The Fifth Circuit:

> State tort causes of action . . . constitute requirements "different from, or in addition to" the [MDA]; they are therefore preempted.

Stamps v. Collagen Corp., 984 F.2d 1416, 1424 (5th Cir.), *cert. denied*, 114 S.Ct. 86 (1993). Accord: *Reeves v. AcroMed Corp.*, 44 F.3d 300 (5th Cir.), *cert. denied*, 115 S.Ct. 2251 (1995); *Feldt v. Mentor Corp.*, 61 F.3d 431 (5th Cir. 1995).

The Seventh Circuit:

> The phrase "any requirement" in 21 U.S.C. sec. 360k(a) is broad enough to include at least some common law causes of action within the [MDA] statute's preemptive scope.

Mitchell v. Collagen Corp., _____ F.3d _____ , 1995 WL 576949 (7th. Cir. Oct. 2, 1995). Accord: *Slater v. Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir.), *cert. denied*, 113 S.Ct. 327 (1992).

The Eighth Circuit:

> The MDA . . . expressly preempts state tort claims involving the safety and effectiveness of Class III devices. . . .

Martello v. Ciba Vision Corp., 42 F.3d 1167, 1169 (8th Cir. 1994). Accord: *National Bank of Commerce of El Dorado v. Kimberly-Clark Corp.*, 38 F.3d 988, 991-92 (8th Cir. 1994).

The Eleventh Circuit:

> The issue is whether section 360k(a) of the [MDA] preempts plaintiffs' state law claims for negligence, strict liability in tort, and the breach of warranty. We . . . conclude that it does.

Duncan v. Iolab Corp., 12 F.3d 194, 195 (11th Cir. 1994). Accord: *Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1342 (11th Cir. 1995).

Not only does the Panel's decision conflict with the holdings of the 17 unanimous panels of the Courts of Appeals that have squarely addressed the issue, and with the *Anguiano* dictum, it is squarely at odds with the preemption jurisprudence of the Supreme Court (*Cipollone v. Liggett Group. Inc.*, 112 S.Ct. 2608 (1992)), and this Court (*Taylor AG Industries v. Pure-Gro*, 54 F.3d 555 (9th Cir. 1995)).

In the judgment of counsel, rehearing *en banc* is required because the Panel's opinion overlooks established MDA law and directly conflicts with the decisions of this Court and the Supreme Court on issues of exceptional importance. The

Panel's decision, if allowed to stand, will impair the integrity of Congress's scheme for regulating medical devices.

III. PETITION FOR REHEARING OR REHEARING EN BANC

A. THE PANEL'S ANALYSIS OF STATE LAW "REQUIREMENTS" IS CONTRARY TO SUPREME COURT AND NINTH CIRCUIT LAW

Before the FDA can approve a Class III medical device for use, it must be demonstrated—by stringent pre-market testing, analysis, and review by qualified independent experts —that (1) the device is safe and effective, and (2) its benefits outweigh its risks. 21 U.S.C. §§ 360e(a)(2), 360c(2). The labeling which accompanies a device—including warnings —must be approved by the FDA. 21 C.F.R. § 814-80. Zyderm, the Class III medical device at issue here, met the FDA's requirements for establishing safety and efficacy, and the FDA approved its labeling. 46 Fed. Reg. 46394 (1981).

The MDA preemption provision states:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). Clearly, a jury verdict for plaintiffs would impose requirements "different from, or in addition to" those imposed by the MDA. As Circuit Judge Posner said

in the first appellate decision to address the preemptive scope of section 360k(a):

> If the FDA in a valid regulation under the Medical Device Amendments requires X, and X relates to safety or effectiveness, a state cannot, whether through statute, regulation, *or common law decision*, require non-X, or X ± Y.

Slater v. Optical Radiation Corp., *supra*, 961 F.2d at 1333 (emphasis supplied).

The Panel held that state tort law does not establish any "requirement" within the meaning of section 360k(a). That holding cannot be squared with the holdings of this Court and the Supreme Court under other, virtually identically worded, federal statutes.

This Court addressed essentially the same issue, as it arises under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), in *Taylor AG Industries v. Pure-Gro*, *supra*, 54 F.3d 555. FIFRA contains a preemption provision mandating that a "State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from" those FIFRA itself requires. *Id.* at 559, 7 U.S.C. § 136v(b). The issue was whether a state common law failure to warm claim—a claim the plaintiffs make here also—would impose a requirement "in addition to or different from" FIFRA labeling requirements.

This Court first looked to the Supreme Court's ruling in *Cipollone v. Liggett Group. Inc.*, *supra*, 112 S.Ct. 2608:

> In *Cipollone*, the Supreme Court held that the preemption provision of the [1969 Cigarette Act] prevents states from imposing tort liability on the basis of inadequate labeling. The preemption provision of the 1969 Cigarette Act states:

> No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter.

The Supreme Court reasoned that "[t]he phrase '[n]o requirement or prohibition' sweeps broadly and suggests *no distinction between positive enactments and the common law*. . . . The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy." *Cipollone*, 112 S.Ct. at 2620.[1]

There is no notable difference between the language of the 1969 Cigarette Act and the language in FIFRA . . . . Like the preemption provision of the 1969 Cigarette Act, [FIFRA] uses the broad term "requirements" to preempt state actions for damages. The Seventh Circuit has noted that "[n]ot even the most dedicated hair-splitter could distinguish these statements. If common law actions can-

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[1] Circuit Judge Reinhardt incorrectly says this is "a proposition endorsed . . . by only a plurality of the Supreme Court in *Cipollone*. . . ." *Kennedy* at 13537 (Reinhardt, J., concurring). In fact, six justices endorsed this proposition. Justice Scalia (with whom Justice Thomas joined) explicitly agreed with the plurality holding on this point: "I agree [with the plurality] that 'the language of the [1969] Act plainly reaches beyond [positive] enactments,' . . .; that the general tort law duties petitioner invokes against the cigarette companies can, as a general matter, impose 'requirement[s] or prohibition[s]' within the meaning of § 59(b) of the 1969 Act, . . .; and that the phrase 'State law' as used in that provision embraces state common law." *Cipollone*, 112 S.Ct. at 2634 (Scalia J., concurring in part and dissenting in part).

> not survive under the 1969 cigarette law, then common law actions for labeling and packaging cannot survive under FIFRA." *Shaw v. Dow Brands. Inc.*, 994 F.2d 364, 371 (7th Cir. 1993).

Taylor AG, 54 F.3d 555, 559-60 (emphasis supplied).

Precisely the same analysis should govern this case. The MDA preemption statement ("any requirement . . . which is different from, or in addition to" the MDA requirements) and the FIFRA preemption statement ("any requirement . . . in addition to or different from" the FIFRA requirements) are substantively indistinguishable. They should be construed and applied in the same manner.

B. THE PANEL UNCRITICALLY RELIED UPON ITS OWN MISTAKEN CONSTRUCTION OF FDA INTERPRETIVE REGULATIONS

In departing from what should have been controlling judicial authority, the Panel followed, as gospel, certain fragments of FDA regulations that it read out of context and plainly misconstrued. Without pausing to consider the meaning of the statutory language on its face—the necessary first step in any conscientious effort at statutory construction—the Panel immediately seized upon an isolated FDA regulatory provision, 21 C.F.R. § 808.1(d), as standing for the proposition that state tort laws, as laws of "general applicability," are not preempted by the MDA. *Kennedy* at 13531-32. This reading of the regulation was wrong for several reasons.

First, the regulatory language upon which the Panel relied (21 C.F.R. § 808.1(d)(1)) is intended as a narrowly tailored exception (one actually found nowhere in the statute) to the broad rule of preemption set forth in the statute and restated in 21 § C.F.R. 808.1(b). As the latter and more general

regulatory provision correctly announces, no state may establish any requirement for a medical device that is different from, or in addition to, the MDA requirements "whether established by statute, ordinance, regulation, *or court decision*. (Emphasis supplied.) As all other Courts of Appeals to have considered the matter have recognized, this regulation openly acknowledges that state tort law, as well as state statutory enactments and regulations, is subject to preemption. See, e.g., *Duvall*, 65 F.3d at 397; *National Bank of Commerce*, 38 F.3d at 991; *Gile*, 22 F.3d at 544 & n.3; *Mendes*, 18 F.3d at 18; *Stamps*, 984 F.2d at 1420-21 & n.1; *King*, 983 F.2d at 1134-35.

Second, FDA explains through examples what 21 C.F.R. § 808.1(d)(1) means by "requirements of general applicability." According to the regulation itself, it is concerned not with tort law but with "requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness), or to unfair trade practices in which the requirements are not limited to devices." *Ibid.* In other words, in the conduct of its business generally, the manufacturer of a Class III device is not immune from local safety codes, contract law, anti-trust statutes, and so forth. State tort rules that would impose constraints on, for example, the manufacture or labeling of Class III devices different from those the MDA and FDA impose, fall well outside the ambit of the exception described in 21 C.F.R. § 808.1(d)(1).

Third, the regulation of course must be construed in a manner consistent with the underlying statute if such a construction is at all reasonable. Instead, the Panel gives the regulation a breadth that "contradicts squarely the manifest intent of the statute which . . . clearly evidences a congressional intent to preempt some common law causes of action." *Mitchell v. Collagen Corp.*, *supra*, 1995 WL 576949 at *6. At bottom, the Panel reads the regulation as endorsing "the

notion that only state laws specifically addressed to [medical devices] are preempted, whereas the [MDA] imposes no constraints on laws of general applicability." *Morales v. Trans World Airlines. Inc.*, 112 S.Ct. 2031, 2038 (1992). As the Supreme Court explained, such a construction "creat[es] an utterly irrational loophole (there is little reason why state impairment of the federal scheme should be deemed acceptable so long as it is effected by the particularized application of a general statute)." *Ibid.* The MDA's preemption provision simply cannot have the meaning ascribed to it by the Panel's misreading of 21 C.F.R. § 808.1(d)(1).

Fourth, if the Panel in fact did read 21 C.F.R. § 808(d)(1) correctly, it should have struck the regulation down, following the Supreme Court's ruling in *Brown v. Gardner*, 115 S.Ct. 552 (1994). In *Brown*, the Supreme Court struck down a Veterans Administration regulation regarding compensation for untoward medical results because the VA's regulation imposed requirements contrary to the plain language of the statute which created the right of action. Here, the FDA's regulation concerning laws of general applicability, 21 C.F.R. § 808.1(d)(1), if interpreted to allow imposition of state requirements related to safety or effectiveness which are different from, or in addition to, the MDA requirements, would be contrary to the express intent embodied in the language of the MDA as drafted by Congress. Therefore, the plain language of 21 U.S.C. § 360k would render void the FDA regulation as so construed.

C. THE PANEL'S HOLDING RESTS ON A PROPOSITION THAT THE SUPREME COURT HAS EXPRESSLY REJECTED

Proceeding from the incorrect notion that the MDA preempts only "a *specific* [state] requirement applicable to a *particular* device," the Panel reasoned that "common law im-

poses only an indirect effect on manufacturers. Defendants in common law damages actions retain the freedom to choose their own response to the legal challenges they face. For example, manufactures facing common law challenges retain the discretion whether to alter their product or whether to bear the cost of any law suits that might result from their decision . . . ." *Kennedy* at 13534. It is telling that the Panel's authority for this construction of the term "requirement" is Justice Blackmun's *dissenting* opinion in *Cipollone*. *Ibid.* A majority of the Court in *Cipollone* expressly rejected the notion that tort liability imposes no requirement on a manufacturer. *Cipollone*, 112 S.Ct. at 2620, 2634. As the First Circuit has explained, the manufacturer's choice of reaction (described by the Panel) "seems akin to the free choice of coming up for air after being underwater." *Palmer v. Liggett Group*, 825 F.2d 620, 627-28 (1st Cir. 1987).

D. THE PANEL' S ANALYSIS OF THE POLICY ISSUES IS WRONG

The Panel began, unfortunately, with a flawed understanding of the federal regulatory scheme. It stated, "[t]here is no opportunity for public comment or for any public challenge to the information presented to the FDA by the device manufacturer." *Kennedy* at 13527. That statement is flatly wrong. The information presented to the FDA is available to any interested person upon request, and any such person may request a formal hearing and contest the FDA's preliminary determination of safety and efficacy. See, e.g., 40 Fed. Reg. 46394 (1981).

The Panel feared that preemption of common law tort claims would "create a rose garden, free from liability, for manufacturers." *Kennedy*, at 13536. This is a significant overstatement that, once again, reveals inattention to the fed-

eral regulatory scheme. The rose garden envisioned by the Panel contains thorns of sufficient number, size, and sharpness to deter uninhibited frolic. "Congress placed enforcement authority in the FDA. The FDA has the broad power: to withdraw approval of a device if it determines that the device is unsafe or its labeling inadequate; to order a recall of the device; and to initiate criminal prosecutions against manufacturers. . . ." *Talbott v. C.R. Bard. Inc.*, *supra*, 63 F.3d at 29 (citations omitted). "In a criminal judgment against a manufacturer, a court may, as part of any sentence, award restitution to those harmed." *Id.* at 30.

Finally, the Panel viewed the statute as having the overriding goal of consumer protection. *Kennedy* at 13536. But Congress's true goal was to encourage and facilitate the development and availability of safe and effective medical devices. Preemption of state tort law has a relevant place in the statutory scheme. The development of new, better, and safer medical devices can be seriously retarded by permitting tort juries to second-guess FDA determinations, and jury awards serve to increase the cost of delivering safe and effective medical help to the public at large.[2]

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[2] See *Brown v. Superior Court*, 44 Cal.3d 1049 (1988); U.S. Congress, Office of Technology Assessment, *Pharmaceutical R&D: Costs. Risks. and Rewards*, OTA-H-522 (Washington, D.C., U.S. Govt. Printing Office, February 1993); L. Lasagna, "The Chilling Effect of Product Liability on New Drug Development," in *The Liability Maze* (P. Huber & R. Litan eds.) (Brookings Institution 1991). The legislative history reveals that Congress had these concerns in mind as well. See *Lohr*, 56 F.3d at 1349.

Congress thus has devised an open regulatory process pursuant to which FDA exercises its expertise in full view of the public and with full opportunity for public participation. The Panel apparently believes that this process should be supplemented by lay jurors in individual cases, who have heard only the bought testimony of partisan opinion witnesses. But Congress did not so provide, and to have done so would have been questionable policy in any event. "Assessment of [public] risks requires close attention to *both* sides of the public risk picture—risks incurred and risks averted, persons harmed and persons helped by the activity in question. The task, in other words, requires a 'public' point of view on the problem. This is a perspective that public agencies can supply and courts plainly cannot." Huber, "Safety and the Second Best: The Hazards of Public Risk Management in the Courts," 85 Colum.L.Rev. 227, 331-32 (1985).

IV. CONCLUSION

Rehearing or rehearing *en banc* should be granted.

Dated: October 31, 1995.

Respectfully submitted,

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